

A study of several hundred benign and neoplastic cervical specimens has shown that MN/CA9 is expressed in all cases of AIS and in more than 90% of cervical squamous neoplasms. High levels of MN/CA9 protein expression were frequently observed in the normal-looking endocervical cells in regions adjacent to dysplastic tissues but the normal cervix does not express MN/CA9 protein. In addition, a study of 305 Pap smears has also indicated that the MN/CA9 expression seen in exfoliative cells in Pap smears recapitulates MN/CA9 expression in the corresponding tissue sections of the cervix. Virtually all atypical glandular cells derived from AIS and adenocarcinoma expressed high levels of MN antigen, whereas endocervical cells obtained from benign cervices were negative (Liao SY, Brewer C, Zavada J, Pastorek J, Pastorekova S, Marietta A, Berman ML, DiSaia PJ, Stanbridge EJ. Identification of the MN antigen as a diagnostic biomarker of cervical intraepithelial squamous and glandular neoplasia and cervical carcinomas. Am. J. Pathol., 1994. 145: 598-609; Liao SY, Stanbridge EJ. Expression of the MN antigen in cervical Papanicolaou smears is an early diagnostic biomarker of cervical dysplasia. Canc. Epid. Biom. Prev., 1996. 5:549-557).



On page 24 please substitute the following for Table 2:

Table 2. Biopsy Follow-Up of Patients with Cytologic Diagnosis of AGUS

Cytologic Diagnosis

Histologic Diagnosis	AGUS-ALL		AGUS-FAVOR		AGUS-NOS		AGUS-FAVOR	
	CATEGORIES		REACTIVE				NEOPLASTIC	
	N=245		N=29		N=157		N=59	
Histologic	No.	(%)	Without	With	Without	With	Without	With
Benign	34	(14)	13	0	20	0	1	0
Atypia*	12	(5)	3	0	8	0	1	0
LSIL	76	(31)	9	1	55	2	7	2
HSIL	95	(39)	1	0	49	18	22	5
Endometrial	3	(1)	0	0	0	0	3	0
Adenoca.								
AIS**	25	(10)	2	0	5	0	17	1

*Atypical squamous metaplasia, atypical reserve cell proliferation, or glandular atypia.

**Coexisting early stromal invasion was seen in 3 cases.

IN THE CLAIMS:

Please cancel Claims 9, 10 and 12.

Please amend Claims 1-8 and 11 as follows:

1. (Amended) A method for determining the presence of cancerous or pre-cancerous cervical lesions from Pap smear cells that have been cytologically diagnosed as atypical glandular cells of undetermined significance (AGUS) under the Bethesda